Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12876

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 4/30/98
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 62322
128.76

A. Patient information

Patient Identifier	2. Age at time of event: 22 or Date of birth: [redacted]	3. Sex	4. Weight
[redacted] In confidence		☐ female ☑ male	160 lbs or ___ kgs

B. Adverse event or product problem

☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

- ☐ death ___ (mo/day/yr)
- ☑ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other: ___

5. Date of event (mo/day/yr): 4/21/98

6. Date of this report (mo/day/yr): 4/24/98

7. Describe event or problem

pt presented 4/21/98 c "racing heart" & anxious mood. pulse 120, B/P 140/104. Pt had taken 6 or 7 "metabolism enhancers" He had taken tablets at 7pm on 4/20/98 & was in our clinic at 8 AM on 4/21/98. He had been unable to sleep during the night. Hands forming into fists/contractions automatically. Reflexes +3 +2 Alert, oriented. Required Im Valiums F/u Rx for oral valium, 5mg.
ASSESSMENT: Tachycardia, Hypertension 2° to ingestion of stimulants.

8. Relevant tests/laboratory data, including dates

9. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA, No chronic health problems, No regular daily medicines taken. Prior P & BP Measurements within Normal Limits

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 RIPPED FUEL (OTC from GNC)
334 mg. Mahaang, 20mg ephedrine, 22% caffeine

2. Dose, frequency & route used
#1 6-7 TABS, ORAL
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 ~~4/20/98~~ APR 20, 1998
#2 in P.M.

4. Diagnosis for use (indication)
#1 Self-PRESCRIBED to stay
#2 AWAKE TO STUDY

5. Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 NOT KNOWN
#2

7. Exp. date (if known)
#1 NOT KNOWN
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
ALSO REQUIRED MEDICAL INTERVENTION. PT SEEN c SYMPTOMS 15 hrs after ~~last~~ DOSE

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
MAY 06 1998

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name & address [redacted] phone # [redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: R.N.

4. Also reported to
☐ manufacturer
☐ user facility
☑ distributor [redacted]

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 1/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.